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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,357	09/22/1998	KLAUS STOCKEMANN	SCH1655	3601

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EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/117,357	STOCKEMANN ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14,20,30,33-36,40,42-47 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11,13,14,20, 33,and 51* is/are allowed.

6)☒ Claim(s) *12,30,35,36,40,44-47,52 and 54* is/are rejected.

7)☒ Claim(s) *34,42,43 and 53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The following is responsive to applicant's status inquiry received Aug. 3, 2004.

Suspension of ex parte prosecution has expired.

Upon further reconsideration of the claims and specification, the following new ground(s) of rejection is respectfully submitted.

The indication of allowability of the claims 11-14, 20, 30, 33-36, 40, 42-45, 47, 51-52, 53-54 is withdrawn in view of the following new ground(s) of rejection.

New Ground(s) of Rejection

Claim Objection(s)

1. Claims 42-43 are objected to because of the following informalities: claims 42 and 43 depend upon cancelled claim 41. Appropriate correction is required.

2. Claims 34 and 53 are objected to under 37 CFR 1.75 as being a substantial duplicate of one another. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 34 and 53 are identical in scope. The compound in claim 53, 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzo[b]thiophene is the chemical name for Raloxifen.

Claim Rejection(s)—35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 35 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 35 recites a method of ameliorating LHRH analogue-induced reduction in bone density in a patient comprising administering to the patient one or more LHRH analogues and Raloxifen wherein the one or more LHRH analogues is " Leuprorelin, Cetrorelix, Buserelin, Antide, Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Lys(mor)-Pro-D-Ala-NH2, Ramorelix, Zoladex or **combinations thereof**." There is insufficient descriptive support for the limitation "combinations thereof." Such a limitation includes a mixture containing all seven of the specific analogues. Other than the administration of a single LHRH analogue, discussed in the examples of applicant's specification (pages 9-11), there is no evidence or direction in the specification, that indicates which one or more of the specific analogues can be mixed together and in what amounts that would render the resulting mixture effective against ameliorating reduction in bone density while avoiding toxicity or adverse side effects. One of ordinary skill in the art would not have concluded that Applicant was in possession of the method as claimed.

4. Claims 44-47, 52, 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method of inhibiting LHRH analog-induced

detrimental side effects due to the administration of an LHRH analog to a patient, comprising administering to a patient in need thereof an effective amount of Raloxifen, i.e. 6-hydroxy-2-(4-hydroxyphenyl)-3-[4-(2-piperidinoethoxy)benzo[b]thiophene. The claimed method of treatment fails to meet the requirement for an adequate written description of the claimed invention as required by 35 USC, 112, paragraph 1.

There is insufficient descriptive support for the claimed methods which require Raloxifen to be administered as the single active agent. The specification describes a combination treatment regimen wherein the one or more LHRH analogue is administered in combination with Raloxifen. Applicant's specification at page 7, paragraph 3 state that treatment with the LHRH analogue is conducted over a period of time and terminated, wherein the anti-estrogen therapy, i.e. Raloxifen is begun. However, paragraph 3 provides that for each component, the period and frequency of administration is selected as indicated in paragraph 1. Yet paragraph 1 on page 6 provides that the LHRH analogue is administered simultaneously with the anti-estrogen.

The claims, as presented, encompass steps, which are outside the scope of those described in the specification. The claims no longer require administering raloxifen in combination with the LHRH analogue so that the bone reducing effects of the LHRH analogue is mitigated by the Raloxifen. The claims currently allow for administration of Raloxifen as a single active agent to treat a patient in which previous treatment with LHRH analogues already caused a reduction in bone density. Other than the combination treatment methods described throughout the specification, no evidence indicates that the methods as claimed were known to Applicant. One of ordinary skill in the art would not have concluded that Applicant was in possession of the claimed method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12, 30, 35, 36, 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "said LHRH analogue" in line 1. There is insufficient antecedent basis for this limitation in the claim. The phrase –one or more—should be added before "LHRH".

Claim 30 recites the limitation "said LHRH analogue" in line 1. There is insufficient antecedent basis for this limitation in the claim. The phrase –one or more—should be added before "LHRH".

Claim 35 recites the limitation "said LHRH analogue" in line 1. There is insufficient antecedent basis for this limitation in the claim. The phrase –one or more—should be added before "LHRH".

Claim 36 recites the limitation "said LHRH analogue" in line 2. There is insufficient antecedent basis for this limitation in the claim. The phrase –one or more—should be added before "LHRH".

Claim 40 recites the limitation "said LHRH analogue" in line 1. There is insufficient antecedent basis for this limitation in the claim. The phrase –one or more—should be added before "LHRH".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM
Nov. 14, 2005

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